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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,851	03/21/2002	Philippe Msika	REGIM-012	2236
7590 11/03/2003			EXAMINER	
Lerner David Littenberg Krumholz & Mentlik 600 South Avenue West Westfield, NJ 07090			FLOOD, MICHELE C	
			ART UNIT	PAPER NUMBER
			1654	8

DATE MAILED: 11/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/088,851

Applicant(s)

MSIKA ET AL.

Examiner

Michele C. Flood

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 21 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☒ Claim(s) 4-31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5. 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are generally narrative and indefinite, failing to conform to current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

Claim 2 recites the limitation "the skin lipids" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claims 1-31 provide for the use of at least one plant oil product, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1-31 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

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Please note that Claims 1-31, as drafted, are generally unsearchable. However, for the sake of expediting prosecution of the application, Claims 1-3 have been examined for prosecution on the merits; and, Claim 1 has been interpreted as reading on a method of making a composition containing at least one plant oil product chosen from the group consisting of oil distillates of plant oil, unsaponifiable materials from plant oil, furan lipids of plant oil and mixtures thereof; and, wherein said composition comprises a cosmetically, pharmaceutically or dermatologically acceptable medium.

Claim Objections

Claims 4-31 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Laigneau et al. (BA, FR 2692783), Montaudoin et al. (BB, FR 2762512), Rancurel (BC, FR 2653974), De Froment (BD, FR 2187328), Huber et al. (BF, EP 0775480), Khaiat (BG, EP 0643960), Aron-Bruntiere et al. (BJ, FR 2405068); Laur et al. (BK, WO 94/21764), Fabre et al. (BO, FR 2724663) and Kaneda et al. (A).

It appears that Applicant claims a method of making a composition containing at least one plant oil product chosen from the group consisting of oil distillates of plant oil, unsaponifiable materials from plant oil, furan lipids of plant oil and mixtures thereof; and, wherein said composition comprises a cosmetically, pharmaceutically or

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dermatologically acceptable medium. It further appears that Applicant further claims a method, wherein the unsaponifiable materials and the oil distillates of plant oil are chosen from the group consisting of unsaponifiable materials and oil distillates are rich in tocopherols and/or phytosterols.

Laigneau teaches a method of making a composition comprising the unsaponifiable fraction of sesame oil mixed with one or more unsaponifiable fractions from any other vegetable oil, e.g., soya oil and wheat germ oil. For example, Laigneau teaches a composition comprising the unsaponifiable fraction of wheat germ oil and the unsaponifiable fraction of sesame oil, which were obtained by molecular distillation of the plant oils (see page 6, line 22 to page 7, line 21). On page 9, lines 1-24, Laigneau teaches that the sesame seed oil comprises linoleic acid (a furan derivative), unsaponifiable fractions, and sterols. Laigneau also teaches that the wheat germ oil comprises unsaponifiable fractions, and sterols (campesterol, stigmasterol, and β -sitosterol), on page 9, line 26 to page 10, line 5. Laigneau further teaches adding the unsaponifiable fractions of plant oils to a physiologically acceptable carrier for the preparation of cosmetic compositions, such as an emulsion, ointment, lipstick, a solar product or restructuring nutritive, anti-wrinkle or day cream. The compositions taught by Laigneau are useful for application to the skin, as nutritional supplement, and to treat the effects of UV- A on the skin.

Montaudoin teaches a method of making a composition containing lupin oil optionally with wheat germ oil or a fraction of wheat germ oil, which has antioxidant and anti-elastase action. The lupin oil was obtained from *Lupinus albus* seeds or flour by

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solvent extraction, and the resultant oil was subjected to molecular distillation to yield an oil comprising unsaponifiable plant material, which may be subjected concentrated by saponifying the mixture and eliminating salts by concurrent extraction to obtain a residue containing sterols and tocopherols. See page 6, line 20 to page 10, line 22. On page 24, in Table 8, Montaudoin also teaches other plant oils which can be used in the making of the referenced compositions, e.g., sunflower oil (tournesol). Montaudoin further teaches that the plant oil products are useful in the making of topically applied skin compositions for the protection of skin against damage to external influences (UVA, UVB, infrared and pollutants) and the effects of aging (wrinkles and loss of skin firmness).

Rancurel teaches a method of making a composition comprising a fraction of soya oil and/or avocado oil, which are combined with pharmaceutically acceptable medium for the preparation of capsules and dietary products. Rancurel teaches that the plant fractions were obtained by molecular distillation of the oils and collecting the distillates. In an example, Rancurel teaches subjecting the plant oils to molecular distillation to obtain a first distillate containing triglycerides, and removing the triglycerides to obtain a fraction enriched in non-saponifiable components, such as sterols and tocopherols, etc. Finally, Rancurel teaches mixing the fractions of soya oil and avocado oil. The products taught by Rancurel have an antagonistic effect with respect to cholesterol and fats, regenerate conjunctive tissues, and retard aging of the skin.

De Froment teaches a method of making a composition comprising unsaponifiable materials from lucerne oil, on page 1 to page 2, line 2. The composition is prepared from dehydrated lucerne by solvent extraction, saponification, and removal of lipids and evaporation. On page 2, lines 6-19, De Froment teaches that the composition contains phytosterols (stigmasterol and sitosterol). De Froment further teaches that the compositions are useful in dermatology cosmetology as an aid to cicatrisation, protection of the skin against sun damage, and for the treatment of ichthyosis.

Huber teaches a method of making a composition by extracting avocado seed or avocado pit, which contains lipid furans, on page 3, line 56 to page 6, line 16. The composition taught by Huber is combined with a pharmaceutically carrier, which is topically applied to skin for the treatment of skin disorders. For example, Huber teaches that the referenced composition comprising furan has profound and beneficial effects on the epidermis and dermis of the skins, significantly moisturizes and smoothes the skin, and enhances the metabolism of skin, on page 4, lines 20-54. Huber further teaches that the referenced compositions are useful for enhancing metabolism of the skin and mucosal tissue, increasing skin thickness

Khaiat teaches a method of making a composition comprising an unsaponifiable faction of soya oil or karate nut butter, a fatty acid triglyceride (obtained from olive oil or sweet almond oil) ; and a hydrolysate of soya or wheat proteins, which are mixed with a pharmaceutically acceptable medium. Khaiat teaches that the referenced compositions are effective in treating areas of dry and/or greasy skin.

Aron-Bruntiere teaches a method of making water in oil emulsions for topical application to skin comprising an unsaponifiable fraction of plant oil (e.g., avocado oil and soya oil; see Claims 4 and 5) containing stigmasterol and alpha-tocopherol. The compositions taught by Aron-Bruntiere are applied to conjunctive tissue for the treatment of dry skin conditions, have anti-scleroatrophic action, prevent formation of toxic peroxides, and stimulate renewal of the epidermis and normalizes formation of corneal cells in the sebaceous pores.

Laur teaches a method of preparing fat fractions of vegetable origin (shea butter) enriched with unsaponifiable materials and tocopherols, on page 3, lines 1-5, which is used for preparing cosmetic and/or dermatological compositions.

Fabre teaches a process for preparing an argan oil enriched in unsaponifiable materials comprising subjecting virgin argan oil to molecular distillation to obtain a distillate enriched with unsaponifiable components (tocopherols and methylsterols) and free fatty acids and purifying the distillate with steam to remove fatty acids. Fabre teaches that the enriched plant oil is used in the making of cosmetic compositions to prevent skin from drying and aging.

Kaneda teaches a method for preparing compositions containing a nonsaponifiable fraction of soybean oil and a pharmaceutical carrier, which is used to treat lipemia. In Column 2, lines 40-54, Kaneda teaches that the nonsaponifiable fraction of soybean oil can be prepared by saponifying and subjecting to molecular distillation a soybean oil. The unsaponifiable soybean oil fraction comprises large amounts of phytosterols (β -sitosterol, stigmasterol and campesterol) and tocopherols

(α -, γ -, and δ -tocopherols), *etc.*

The references anticipate the claimed subject matter.

Claims 1 and 3 are rejected under 35 U.S.C. 102(e) as being anticipated by Moy (B).

Applicant's claimed invention was set forth above.

Moy teaches a method of preparing a dermatological composition comprising unsaponifiable avocado seed lipids, in Column 4, lines 25-37. In Column 3, lines 54-61, Moy teaches that the unsaponifiable material of avocado oil contains sterols (stigmasterol, sitosterol and campesterol). The composition taught by Moy are used in the making of topical compositions for the skin, which are used for treating skin keratoses or striae distensae, and eliminating or reducing size of skin lesions.

The reference anticipates the claimed subject matter.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Courtin (BH, FR 443835),


Applicant's claimed invention of Claims 1 was set forth above.

Courtin teaches a method of making a composition comprising unsaponifiable materials obtained from soya oil and avocado oil, on page 1, lines 30-40. Courtin further teaches that the materials are used in the making of cream that softens skins, protects skin from the effects of aging, and has cicatrisation activity.

The reference anticipates the claimed subject matter.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-9432. The examiner can normally be reached on Monday through Friday from 7:15 am to 3:45 pm. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Brenda Brumback whose telephone number is (703) 306-3220.


MICHELE FLOOD
PATENT EXAMINER
MCF

October 31, 2003